

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Sec.

860.1 Scope.

860.3 Definitions.

860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

860.7 Determination of safety and effectiveness.

Subpart B—Classification

860.84 Classification procedures for “old devices.”

860.93 Classification of implants, life-supporting or life-sustaining devices.

860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Reclassification

860.120 General.

860.123 Reclassification petition: Content and form.

860.125 Consultation with panels.

860.130 General procedures under section 513(e) of the act.

860.132 Procedures when the Commissioner initiates a performance standard or pre-market approval proceeding under section 514(b) or 515(b) of the act.

860.134 Procedures for “new devices” under section 513(f) of the act and reclassification of certain devices.

860.136 Procedures for transitional products under section 520(l) of the act.

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Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures

governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commissioner* means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

(c) *Class* means one of the three categories of regulatory control for medical devices, defined below:

(1) *Class I* means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

(2) *Class II* means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish